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EXAMINER

MOE ZIE, F

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

08/28/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/469,733

Applicant(s)
Etter

Examiner
F. MOEZIE

Art Unit
1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 7, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 and 5 20) ☐ Other:

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DETAILED ACTION

STATUS OF CLAIMS

Claims 1-48 are pending prosecution in this Office action.

The Amendment and Remarks filed 6/7/01, paper no. 8, in response to the Office action - Restriction Requirement mailed 3/27/01, paper no. 6, have been considered and found persuasive. Hence, claims 1-48 are examined on their merits in this Office action.

REJECTION -35 U.S.C. 112, FIRST AND SECOND PARAGRAPHS

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 20-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polylactic acid of specified MW (see Table 2), does not reasonably provide enablement for other polymer of all molecular weights, be it natural or synthetic. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention **without undue experimentation**. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Foreman*, 230 USPQ 546 (Bd App 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction and guidance provided,
- 3) The presence or absence of working examples,
- 4) The nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art ‘
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicant fails to set forth the criteria for selecting the “first organic solvent” and “second organic solvent” that are mutually soluble. The information such as “first” and “second” does not distinguish one solvent over the other and is not indicative of the structure/function for either solvent. Note: for the first solvent DMSO and DMFA and for the second solvent only lower alkyl alcohols are enabled by the instant disclosure. Furthermore, the claimed “compressed anti-solvent fluid” fails to show the required properties for the useful anti-solvent(s).

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The instant application shows the use of compressed carbon dioxide only. The use of carbon dioxide for producing protein particles is taught by Yeo et al "Formation of Microparticulate Protein Powders Using a Supercritical Fluid Antisolvent" in *Biotechnology and Bioengineering*, Vol. 41, pp 341-346 (1993). With respect to insulin the reference teaches the feature that the compressed anti-solvent must have in order to be useful in "Figure 1 shows the volumetric expansion of dimethylsulfoxide (DMSO) when contacted with carbon dioxide", page 347, 1st col. 1st paragraph. Hence, the volumetric expansion of the solvent used is one of critical features for selecting a suitable anti-solvent. Clearly, all compressed anti-solvents as claimed are not enabled by the instant disclosure and the defemination of the useful anti-solvents depend on the solvent being removed and would require undue experimentation. Hence, the claims ought to be limited to the enabling disclosure.

Applicant fails to set forth the criteria for making a multi-component insulin containing particles comprising a polymer. Additionally, applicant fails to provide information allowing the skilled artisan to know the molecular structure/function, Molecular Weight ranges required for the claimed particle formation. Further, applicant fails to cite the unique proportions of ingredients that results in any considerable degree of insulin encapsulation. The instant method claims read on an admixture of components and the process for making a useful insulin encapsulated multi-component particle necessitate an exhaustive search for determining the conditions and the relative proportions of the component. Finally, there is no guidance as to how

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an art skilled would separate the insulin containing particles or the insulin containing (multi-component(s)) particles as claimed.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite as it encompasses too many open-ended terms such as, “comprising”; “containing” (twice); “including” (twice) in less than a total of five lines of the claim.

In claim 1, the only independent claim in this file, the terminology “cosolvent system” renders the claim indefinite as to the “system” being claimed. Clearly, the claim calls for two solvents that are miscible with one another and there is no “system” per-se involved anywhere in the process. Deletion of the term “system” is suggested (claims 4 and 5).

The claims are indefinite and confusing regarding “the first organic solvent “ and “the second organic solvent” designations, such designations fails to distinguish one solvent over the other in any practical sense. Furthermore, applicant has used these terms interchangeably in the

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claims. Note: **For example**, in claims 8 and 9, "second organic solvent" is an alcohol whereas in claims 25, 26 and 27, the "first organic solvent" is an alcohol.

In claim 14 the term "amphiphilic materials" render the claim indefinite as to which "materials" are intended to claim in the claim.

In claim 35 the term "first" (line 1) render the claim confusing and is excessive. Cancellation of the term is suggested, and on the line 2, the term "dissolving the acid with" should be "dissolving the acid in" which would be in agreement with "dissolving the insulin in" which occurs on the same line of the claim.

5. The following terms in the claims are relative terms which render the claims indefinite.

The examples for such terms are: "at least" (claim 1); "more soluble" (claim 2); "greater than" (claims 3, 10, 39, 45); "less than" (claim 5); "substantially" (claim 14, 21 and 38); "larger than" or "greater than" (claims 15, 46 and 47); "at least a portion" (claim 19).

The above terms are not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "so that" in claims 46 and 47 render the claims indefinite and incomplete as to how. The missing step as to how must be set forth in the claims for completeness.

The references cited are relevant to this case.

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CONCLUSION

No claim is allowed.

Any inquiry concerning this communication should be directed to F.T. Moezie at telephone number (703) 305-4508 or Dr. LOW (SPE) at 308-2923.

F.T. Moezie
F.T. MOEZIE, PH.D.
PRIMARY EXAMINER
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